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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,055	04/27/2005	Minoru Takebe	211A 3658 PCT	9042

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KODA & ANDROLIA  
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SUITE 1140  
LOS ANGELES, CA 90067

EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,055	<b>Applicant(s)</b> TAKEBE ET AL.	
	<b>Examiner</b> Jennifer Kim	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

The amendment filed April 27, 2007 have been received and entered into the application.

### **Action Summary**

The rejection of claim 4 under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicants' amendment canceling the claim.

The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Takebe et al. (U.S. Patent No. 5,885,632) is hereby expressly withdrawn in view of Applicant's persuasive argument.

The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Takebe et al. (U.S. Patent No. 6,045,819) is hereby expressly withdrawn in view of Applicant's persuasive argument.

The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Takebe et al. (U.S. Patent No. 6,303,161 B1) is hereby expressly withdrawn in view of Applicant's persuasive argument.

The rejection of claims 1, 2 and 4 under 35 U.S.C. 102(e) as being anticipated by Obata et al. (U.S. Patent No. 6,444,239 B2) is being maintained for the reasons stated in

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the previous Office Action. However, this rejection is modified to exclude cancelled claims 2 and 4 and include newly added claim 5.

The rejection of claims 1-4 under 35 U.S.C. 102(e) as being anticipated by Kelly et al. (U.S. Patent No. 6,642,212) is hereby expressly withdrawn in view of Applicant's persuasive argument.

Rejections of claims 1- 4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of U.S. Patent No. 5,885,632; unpatentable over claim 7 of U.S. Patent No. 6,045,819; and unpatentable over claim 1-9 of U.S. Patent No. 6,303,161 are hereby expressly withdrawn in view of applicants filing of Terminal Disclaimer.

The provisional rejections of claims 1-4 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-13 and 15 of copending Application No. 10/070888; unpatentable over claims 1-7 of copending Application No. 10/070889; and unpatentable over claims 1-7 of copending Application No. 10/070889 are hereby expressly withdrawn in view of applicants filing of Terminal Disclaimer.

Upon further consideration, following new grounds of rejection has been made. Accordingly, this rejection is made non-final.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Obata et al. (U.S. Patent No. 6,444,239 B2) of record.

Obata et al. teach a product comprising 480g of isoflavone aglycone powder comprising an **isoflavone aglycone content of 52%**, which was found to be made up of 54% of genistein, 40% daidzein, and 6% of glycitein. (Example 3, column 5).

Accordingly, Applicant's recitation in claim 1 of the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by cited prior art comprising 54% of same active agent of isoflavone aglycone comprising overlapping and encompassing the instantly claimed at least 30 wt %. Further, Applicants' recitation in claim 1 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition taught by the prior art.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being unpatentable by The Merck Index, tenth edition. (1983), (Merck).

Merck teaches that daidzein obtained from soybean. It is noted that the content of (pure) daidzein taught by prior art encompasses Applicant's amount set forth in claims 3 and 5.

Accordingly, Applicant's recitation in claim 1 of the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by cited prior art comprising pure form of same active agent of isoflavone aglycone (daidzein) comprising overlapping and encompassing the instantly

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claimed amounts. Further, Applicants' recitation in claim 1 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition taught by the prior art.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being unpatentable by Potter et al. (U.S. Patent No. 5,855,892).

Potter et al. teach pharmaceutical formulation of daidzein as an active agent. Potter et al. teach gelatin capsules comprising 10-1000mg of daidzein in a capsule and a tablet. Potter et al. also teach daidzein in 10-1000mg/5ml in a suspension. (column 7, under Formulations and formulations 1-3). These amounts of daidzein contained in the formulations overlap and encompasses Applicants' claimed amount of isoflavone aglycone at least 30%wt and at least 70wt% daidzein.

Accordingly, Applicant's recitation in claim 1 of the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by cited prior art comprising same active agent of isoflavone aglycone (daidzein) comprising overlapping and encompassing the instantly claimed amounts. Further, Applicants' recitation in claim 1 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition taught by the prior art.

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None of the claims are allowed.

### ***Response to Arguments***

Applicant's arguments filed April 27, 2007 have been fully considered but they are not persuasive. Applicant argues that Obata et al. does not state whether the product is expressed in volume percentages, weight percentages or molecular percentages. This is not found persuasive because Obata et al. teach that 480g of an **isoflavone aglycone powder** was obtained in their Example 3, and that **52%** of which was found to be made up of **54%** of genistein, **40%** of daidzein and **6%** of glycitein. Therefore, this teaching clearly anticipates claimed wt% set forth in claim 3 because an isoflavone aglycone powder obtained by Obata et al. was measured in **grams**.

Applicant further argues that claims 1 and 5 are not anticipated by Obata et al. because Obata et al. does not disclose a daidzein content of 70 wt% or greater. This is not found persuasive because the limitation of "at least 70 wt% daidzein" appears in claim 3. However, Obata et al. reference was applied under 35 USC 102 for the claims 1, 2 and 4 in the previous Office Action. The rejection of claims 1, 2 and 4 under 35 USC 102 as being anticipated by Obata et al. in the previous Office Action was deemed proper because Obata et al. clearly teach a product comprising isoflavone aglycone (claim 1), wherein the isoflavone aglycone is comprised of 40% daizein (example 3). Newly added claim 5 is also anticipated by Obata et al. because the newly added claim

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5 is drawn to a composition comprising isoflavone aglycone concentrate at least 30 wt%. It is noted that Obata et al. teach a product comprising 480g of isoflavone aglycone powder comprising an **isoflavone aglycone content of 52%**, which was found to be made up of 54% of genistein, 40% daidzein, and 6% of glycitein. (see above rejection). Applicant argues that Obata et al. does not disclose superoxide scavenging activity. This is not persuasive because Applicant's recitation of the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by cited prior art comprising pure form of same active agent of isoflavone aglycone comprising overlapping and encompassing the instantly claimed amounts. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for




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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kim  
Patent Examiner  
Art Unit 1617

Jmk  
July 30, 2007